

ABSTRACT

The present invention relates to pH-sensitive mucoadhesive film-forming gels and wax-film composites suitable for topical and mucosal delivery of molecules of interest, namely active pharmaceuticals. The gels comprise a pharmaceutically acceptable pH-sensitive polymer that responds to a lowering of pH by precipitating into films when in contact with the skin or mucosal surface. The films also comprise an adhesive polymer that allows the film to remain in contact with the tissue for an extended period of time. The wax-film composites comprise a bi-layer film having both the said pH-sensitive mucoadhesive layer to promote strong adherence to the skin and mucosal surfaces as well as a specially bonded wax layer intended to extend the adherence of the film to tissues for a prolonged period of time. The invention also relates to the use of said pH-sensitive film-forming gels and wax-film composites to deliver molecules of interest, such as small molecules, peptides, proteins, and nucleic acids either locally to act at the site of administration or for the absorption of said molecules of interest across biological membranes into the systemic circulation.

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